JUN - 6 2003

510(k) SUMMARY
as required per 807.92(c)

1. **Submitters Name, Address**:

Siemens Medical Solutions, Inc.
Electromedical Systems Group, PCS
Danvers, MA 01923
Tel: (978) 907-7500
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Official Correspondent: Connie Hertel, Director
Quality Assurance & Regulatory Affairs
Contact person for this submission: Penelope Greco
Date submission was prepared: March 7, 2003

2. **Trade Name, Common Name and Classification Name**:

A. **Trade Name**:

SIEMENS INFINITY MultiView WorkStation™ Telemetry System with TruST™

B. Common Name, Classification Name, Class and Regulation Number:

Common Name	Classification Number	Class	Regulation Number
Monitor, Physiological, Patient (with arrhythmia detection or alarms)	MHX	III	21 CFR 870.1025
Radiofrequency physiological signal transmitter and receiver	74DRG	II	21 CFR 870.2910
Cardiac monitor	74DRT	II	21 CFR 870.2300
Pulse rate monitor	74BWS	II	21 CFR 870.2300
Pulse oximeter	74DQA	II	21 CFR 870.2700
Breathing Frequency Monitor	73BZQ	II	21 CFR 868.2375
Clinical Electronic Thermometer	80BWX	II	21 CFR 880.2910
Indwelling Blood Pressure Monitor	74CAA	II	21 CFR 870.1110
Heart Rate Monitor, Neonatal	74FLO	II	21 CFR 870.2300
Ventilatory Effort Monitor (Apnea Detector)	73FLS	II	21 CFR 868.2375
Monitor Blood Pressure, Neonatal, Invasive	74FLP	II	21 CFR 870.1110
Arrhythmia detector & Alarm	74DSI	III	21 CFR 870.1025
Medical Cathode-Ray Tube Display	74DXJ	II	21 CFR 870.2450
ST Segment Monitor with Alarm	74MLD	III	21 CFR 870.1025
Non-indwelling Blood Pressure Monitor	74DXN	II	21 CFR 870.1130
End-tidal Carbon-Dioxide Monitor	73CCK	II	21 CFR 868.1400

3. **Predicate Device Identification**:

Philip's (HP) Viridia Component Monitoring System with EASI™ ST Segment– 510(k) K992595
INFINITY MultiView WorkStation Telemetry System Modification – K024108
INFINITY MultiView WorkStation Modifications – K022889
SC 9000 / SC 9015 Enhanced with 12-Lead ST Segment Analysis – 510(k) K974698
MultiView WorkStation Enhanced with Diagnostic Statement (Rest ECG) – 510(k) K980625
SC 7000 / SC 9000XL Infinity Modular Bedside Monitors – 510(k) K982730
SC 8000 w/Advanced Communication Option – 510(k) K990563

4. **Device Description**:
Siemens' INFINITY MultiView WorkStation Telemetry with TruST enables continuous 12-lead ECG monitoring with a reduced number of electrodes. With TruST only 6 lead wires are required to acquire 12 leads of ECG. TruST relies on conventional lead placement and the INFINITY TruST telemetry transmitters. The TruST matrix uses general reconstruction coefficients to compute 4 precordial leads.

5. **Intended Use**:
The INFINITY MultiView WorkStation (MVWS) Telemetry System is intended to measure and produce visual and audible alarms for one or more physiological parameters

The INFINITY MVWS telemetry System with TruST is intended for 12-Lead ECG monitoring with a reduced set of electrodes. Reconstructed leads are intended for real-time assessment of ST segment changes.

This device is intended for use in an environment where patient care is provided by Healthcare Professionals, i.e. Physicians, Nurses, and Technicians, who will determine when use of the device is indicated, based upon their professional assessment of the patient's medical condition.

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6. Table of Device Similarities and differences to predicate device

	Substantial Equivalent Device HP Viridia Component Monitoring System with EASI™ ST Segment Measurement	Substantial Equivalent Device SC 9000 / SC 9015 Bedside Monitoring System Enhanced with 12-Lead ST Segment Analysis	Applicant Siemens Medical Systems Infinity MultiView WorkStation Telemetry System with TruST	Explanation of Differences
Manufacturer	Philips (HP)	Siemens Medical Solutions	Siemens Medical Solutions	
510(k) Number	K992595	K974698	To be assigned	
Intended Use	Assessment of real time ST segment analysis in adult patients.	To determine the ST Segment of the ECG signal and to compute the deviation of this ST Segment from the iso-electric point (baseline).	The INFINITY MultiView WorkStation (MVWS) Telemetry System is intended to measure and produce visual and audible alarms for one or more physiological parameters The INFINITY MVWS telemetry System with TruST is intended for 12-Lead ECG monitoring with a reduced set of electrodes. Reconstructed leads are intended for real-time assessment of ST segment changes.	Similar to Philips' Easi in that the MVWS with TruST monitors 12-lead ECG with a reduced set of electrodes.
Intended Population	Adult	Adult/Pediatric	Adult/Pediatric	
Intended Environment	In the medical clinic or hospital environment for use by physicians, nurses and ECG technicians.	Same	Same	
Diagnostic	No	Yes	No	
ST Analysis	Up to 12 Derived Complexes	Up to 12 Measured ST Complexes	Up to 8 Measured ST Complexes Up to 4 Derived ST Complexes	dV1, dV3, dV4, dV6
Electrodes	5	12	6	

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7. Assessment of non-clinical performance data for equivalence:
   Currently there are no FDA standards for this device.

8. Assessment of clinical performance data for equivalence:
   Section J

9. Biocompatability:
   Not applicable

10. Sterilization:
    Not applicable

11. Standards and Guidances: Section P

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 6 2003

Ms. Penelope H. Greco
Regulatory Submissions Manager
Siemens Medical Solutions, Inc.
Electromedical Systems Group, PCS
16 Electronics Avenue
Danvers, MA 01923

Re: K030738
Trade Name: MultiView WorkStation Telemetry System with TruST™
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia detector and alarm
Regulatory Class: Class III (three)
Product Code: MHX
Dated: March 7, 2003
Received: March 10, 2003

Dear Ms. Greco:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K030738

Device Name: Siemens Infinity MultiView WorkStation Telemetry System Enhanced with TruST™

Indications for Use:

Use of the INFINITY MultiView WorkStation Telemetry System is indicated for adult and pediatric patient populations in an environment where patient care is provided by Healthcare Professionals (Physicians, Nurses, Technicians) when the professional determines that a device is required to measure and produce visual and audible alarms for any one or more of the following parameters:

- Heart rate
- ECG Arrhythmia Analysis
- Arterial oxygen saturation
- Pulse rate
- ST segment analysis

The INFINITY MultiView WorkStation (MVWS) Telemetry System with TruST is indicated for use when 12-Lead ECG monitoring with a reduced set of electrodes is desired. Reconstructed leads are intended for real-time assessment of ST segment changes.

MRI Compatibility Statement:

The Infinity MultiView WorkStation Telemetry System is not compatible for use in a MRI magnetic field.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K030738